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Isolators or Cytotoxic Drug Safety Cabinets: Unpacking the science in selection choices for pharmacy applications

Introduction:

In the handling of cytotoxic drugs, the choice of containment equipment significantly impacts both the safety and efficacy of drug preparation. While pharmaceutical isolators have been a mainstay in this sector, recent findings indicate a compelling case for the preferential use of cytotoxic drug safety cabinets. This article aims to constructively argue the benefits of cytotoxic drug safety cabinets over pharmaceutical isolators, delving into aspects of microbial growth, operational efficiency, and practicality.

Applicable Standards:

The Australian Standard was the first of its kind for Cytotoxic Drug Safety Cabinets or CDSC's as they are commonly referred. Australia first recognized and then developed a standard specifically for this type of safety cabinet during the 1970's. Today the Australian Standard that governs the design, construction and usage of CDSC's is AS 2252.5. There is also DIN 12980, a German Standard first developed in 2012 that demonstrates the growing prevalence of this type of cabinet within Europe.

Critical performance tests

- Filter Installation Integrity: Filter integrity is determined by: AS 1807:2021 Cl 4.4 determination of integrity of terminally mounted HEPA and AS 1807.7 determination of integrity of non- terminally mounted HEPA.
- Containment at the aperture: Containment at the aperture is determined by either AS 1807:2021 Cl 4.9 air barrier containment or AS 1807:2021 Cl 4.12 air barrier test
- Work Zone Integrity: Tested in accordance to AS1807:2021 Cl 4.3 Determination of work zone integrity
- Air velocity and uniformity in the workzone: Tested in accordance to AS 1807:2021 Cl 4.1 determination of air velocity and uniformity
- Alarm Operational Adjustment: Tested in accordance to preset systems by the manufacturer.
- Particle counts: Particle counts are tested at the working positions of the workzone to ISO 14644.1

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Operational Training and Experience: (Hospital Pharmacy Europe, ‘Contamination during cytotoxic drug preparation’:

The comparative analysis of microbial growth in pharmaceutical isolators and cytotoxic drug safety cabinets is crucial for determining the optimal equipment for handling cytotoxic drugs. Pharmaceutical isolators, with their sealed and enclosed design, offer significant protection against external contamination but pose higher risks for microbial contamination. This is attributed to the inherent challenges in cleaning and removing contaminants from these systems, as well as the complex procedures required for material transfer, potentially increasing microbial ingress. A study in Hospital Pharmacy Europe revealed that isolators had a higher rate of contaminated settle plates (12%) compared to cytotoxic drug safety cabinets (4%), though the difference was not statistically significant (p=0.06), indicating a tendency for higher microbial growth in isolators. Furthermore, the study highlighted the impact of the learning curve associated with isolator usage, suggesting that initial higher contamination rates could decrease as technicians gain proficiency with the technology (‘Contamination during cytotoxic drug preparation,’ Hospital Pharmacy Europe). This research underscores the need to carefully weigh the design and operational attributes of these systems in managing microbial risks.

[Read the full article on Hospital Pharmacy Europe](https://hospitalpharmacyeurope.com) for more detailed information.

Complex Cleaning and Maintenance:

A primary consideration in any pharmaceutical setting is the ease of cleaning and maintenance of the equipment used. Pharmaceutical isolators, with their enclosed design, pose a unique challenge in this regard. The intricate nature of these isolators often leads to difficulties in accessing all interior areas, which is crucial for thorough cleaning and maintenance. In contrast, cytotoxic drug safety cabinets, with their more open and accessible design, allow for more straightforward and effective cleaning processes. This difference is not just a matter of convenience but a critical factor in controlling microbial growth within these environments.

Material Transfer Process: (Hospital Pharmacy Europe, ‘Guide to workstations for cytotoxic handling’):

Another key factor is the process of transferring materials into and out of the containment system. Pharmaceutical isolators typically involve a complex, multistage process for material transfer. Each stage in this process presents potential risks for microbial contamination, especially if not conducted with precision. Cytotoxic drug safety cabinets offer a more simplified and direct approach to material transfer, thereby reducing the cumulative risk of contamination at each stage. This simplicity not only enhances the safety profile but also increases the efficiency of the drug preparation process.

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Initial and ongoing costs of operating an Isolator:

Pharmaceutical isolators, with their complex design and advanced technology, typically come with a higher initial purchase price. This higher cost is attributed to the complex engineering required to maintain a completely sealed environment, which is crucial for ensuring the safety and efficacy of the drugs being handled. Additionally, the ongoing maintenance costs for isolators are considerably higher due to their intricate components and the necessity for specialized cleaning procedures. These maintenance activities often require trained personnel and can be more time-consuming, further adding to the operational expenses. In contrast, cytotoxic drug safety cabinets, while still adhering to stringent safety standards, are generally less complex in their design and functionality. This simplicity not only reduces the initial purchase cost but also makes them more cost-effective to maintain over time. Therefore, for facilities operating with budget constraints or those that prioritize cost-efficiency without compromising safety, cytotoxic drug safety cabinets can be a more financially viable option compared to pharmaceutical isolators.

About AES Environmental:

AES Environmental, nestled in the heart of Sydney, NSW, is a proudly family-operated manufacturing buinsees. We specialise in producing Laminar Flow Laboratory Products, right here in Sydney. Our expertise doesn't stop there – we're also masters in Air Filtration, with manufacturing arms spread across Sydney, Adelaide, Perth, Thailand, and the UK. Under our wing, we've got a range of stellar brands like Clyde-Apac, Vokes, AES Environmental, and Email Air Handling. With a dedicated team of between 50-100 passionate folks, we're all about pioneering the future of contamination control equipment. It's not just what we do; it's our commitment to a cleaner, safer world.

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Conclusion:

While pharmaceutical isolators have their merits, particularly in their high containment capabilities, cytotoxic drug safety cabinets present a compelling case for their use, especially when considering factors like initial and life-cycle costs, ease of cleaning, simplicity in material transfer, and operational training. The reduction in microbial contamination risks, coupled with improved operational efficiency, positions cytotoxic drug safety cabinets as a preferable choice in many pharmaceutical settings. This preference does not diminish the role of isolators but rather highlights the importance of selecting the right tool for the right task, with an emphasis on practicality, safety, and efficiency in the handling of cytotoxic drugs.